

REMARKS

Claims 1 and 4-57 are currently pending in this application. Claims 29-33 and 53-55 stand withdrawn. Claims 1, 18-28 and 57 are canceled herein without prejudice. Applicants respectfully reserve the right to pursue the subject matter of the canceled claims in one or more continuation or divisional applications. Claims 4-17, 34-52 and 56 are amended herein. Claims 4-17 and 29-56 will be pending on entry of the current amendments.

Support for the amended claims can be found throughout the specification as originally filed, *inter alia*, in canceled claim 1, the subject matter of which has been incorporated into pending claim 13; on page 7, lines 3-19, and in Example 1, Experiments 1 and 2. Accordingly, Applicants submit that no new matter is introduced by way of the present amendments.

Applicants also respectfully note that the previous response submitted on February 02, 2004, inadvertently misquoted the M.P.E.P. Specifically, the quoted language in response to the claim rejections under 35 U.S.C. § 103 stated in pertinent part “knowledge generally available to one skilled in the art.” However, the exact language in the M.P.E.P. corresponding to this quote, recites “knowledge generally available to one of ordinary skill in the art.” *See* M.P.E.P. § 2142.

Rejections

Rejections under 35 U.S.C. § 112, 2nd paragraph

Claims 8 and 9 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. The Office Action states that the recitation of the term “about” is unclear.

Applicants respectfully disagree and traverse this rejection.

According to the CCPA, “it is well established that ‘claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their ‘broadest *reasonable* interpretation.’’’ *In re Marosi*, 710 F.2d 799, 802, 218 U.S.P.Q. (BNA) 289, 292 (CCPA 1983) (*quoting In re Okuzawa*, 537 F.2d 545, 548, 190 U.S.P.Q. (BNA) 464, 466 (CCPA 1976)).

“Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim invalid.”

Seattle Box v Ind. Crating and Packing, 731 F.2d 818, 826, 221 USPQ 568, 573-574 (Fed. Cir. 1984). Regarding issues of definiteness of claim language, particularly the term “about”, “the question becomes whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification.” BJ Services v. Halliburton Energy Services, 338 F.3d 1368, 67 USPQ2d (BNA) 1692 (Fed. Cir. 2003).

Applicants submit that the term “about” has a well-established meaning and is understood by those of skill in the art. For example, the American Heritage® Dictionary of the English Language, Fourth Edition (2000) (downloaded from www.dictionary.com on September 16, 2005) defines the term as “approximately, nearly, almost”. A copy of this definition is attached herewith as the Appendix.

Applicants further submit that the Office Action misconstrues the remarks on page 16 of the Response filed February 02, 2004. The Office Action interprets this remark out of the context of the entire sentence which reads: “While not definite, Applicants assert that one of skill in the art reading the claim language and the specification in its entirety would understand that the claim recitation of ‘...about two hours...’ includes a reasonable degree of time duration either greater than or less than two hours, but substantially two hours in length.” Response, pages 16-17. This is not an admission that “about” is indefinite, but a discussion of the meaning of the term as it is understood in the art. Applicants submit that one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 8 and 9 under 35 U.S.C. § 112, 2nd paragraph.

Claim 34 was rejected under 35 U.S.C. §112, second paragraph. Applicants have amended claim 34 to clarify that the *Lactococcus lactis* subsp. *lactis* strain CHCC373 deposited under accession number DSM 12015 is the lactic acid bacterial cell that is to be modified (See pp. 9 lines 1-5 of the specification).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 34 under 35 U.S.C. § 112, 2nd paragraph.

Claims Rejections- 35 U.S.C. §112, first paragraph

Claims 1, 4-17, 34-52, 56 and 57 were rejected under 35 U.S.C. § 112, 1st paragraph, for the scope of enablement. More specifically, claims 1, 4-17, 34-52, 56 and 57 were rejected as allegedly lacking enablement for lactic acid bacterial cells modified to contain at least 0.1 ppm of any porphyrin containing compound. Claim 5 was rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for lactic acid bacterial cells modified when treated under anaerobic conditions. Claims 8 and 9 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for making cells that will be effective when inoculated in a concentration of 10⁷ cells/ml into low pasteurized skim milk having 8 ppm of dissolved oxygen. Claims 9 and 10 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for lactic acid bacterial cells modified when treated under anaerobic conditions. Claim 12 was rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for lactic acid bacterial cells modified when treated under anaerobic conditions. Claim 16 was rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for lactic acid bacterial cells modified to contain at least 0.1 ppm of any porphyrin containing compound using pure strains. Claims 40-42 and 45-47 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for making and/or using the invention at “at least 60 ppm or higher of a porphyrin-containing compound”, or “at least 40 ppm or higher of a cytochrome”, respectively. Claims 48-52 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for cells otherwise treated that reduce the amount of dissolved oxygen at greater than 35% per hour. Since claims 1 and 57 are cancelled, rejections thereof are moot.

Applicants respectfully disagree and traverse this rejection.

It is well established under 35 U.S.C. §112 ¶ 1, that “[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” (*United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1986)). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), MPEP § 2164.01.

Applicants respectfully submit that their specification enables one of ordinary skill in the art to practice the claimed invention for all the reasons discussed during prosecution of this application, e.g., *see* pages 12-16 of the Request for Extension of Time and Response to Office Action mailed August 1, 2002, filed by Applicants on February 2, 2004, which are incorporated

herein by reference. In addition, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 of Mr. Asger Geppel, a named inventor in the present application. Based on his educational background and his industrial experience, Mr. Geppel considers himself a person of ordinary skill in the technology of lactic acid bacterial cells and modification thereof. According to Mr. Geppel, a person of ordinary skill in the art understands “porphyrin compound” to be a generic name for a group of cyclic tetrapyrrole derivative compounds whose structures are derived from that of porphyrin by substitution at the carbon atoms located at the apices of the pyrrole core with various functional groups, and are widely distributed in plants and animals. In Mr. Geppel’s opinion a person of ordinary skill knows that different iron containing porphyrin compounds share the same chemical core structure. *See Declaration, paragraphs 6 and 14.* The Declaration identifies haeme, haemin, cytochrome and hemoglobin as examples of iron containing porphyrin compounds. *See Declaration, paragraph 7.*

Mr. Geppel discusses the production of lactic acid bacterial cells comprising an iron containing porphyrin compound by adding haemin to the fermentation medium under both aerobic and anaerobic conditions. *See Declaration, paragraph 11.* According to the Declaration, “[s]ince all types of iron containing porphyrin compounds are closely related (*See* specification, page 7, lines 14-16), it is my opinion that the invention should work for all types of iron containing porphyrin compounds.” *See Declaration, paragraph 12.* The Declaration further states that “pure” haemin does not need to be used to make LAB cells which comprise an iron containing porphyrin compound, but that other haeme proteins from animal sources, such as blood, could be used. *See Declaration, paragraph 8.*

Mr. Geppel states that “[i]n my opinion, by demonstrating that iron containing porphyrin compounds are comprised by the cells when they are grown in a medium containing haemin, the inventors have enabled the invention for all iron containing porphyrin compounds. In particular, based on the specification, including the examples, it is my opinion that I would be able to make LAB cells comprising an iron containing porphyrin ring when cultured in a fermentation medium containing any of the iron containing porphyrin compounds in any effective amounts desirable, without undue experimentation, if any were needed.” *See Declaration, paragraph 11.*

As a person of ordinary skill in the art, Mr. Geppel states that if the LAB cells treated with an iron containing porphyrin compound (e.g., haemin) can comprise and maintain an iron containing porphyrin ring derived from that or a similar iron containing porphyrin compound, it

is Mr. Geppel's opinion that the person skilled in the art would understand that LAB cells can comprise and maintain an iron containing porphyrin ring derived from other sources (e.g., synthetically made), and work in a similar way. See Declaration, paragraph 14.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4-17, 34-52, and 56 under 35 U.S.C. § 112, 1st paragraph, for the scope of enablement.

Claims Rejections- 35 U.S.C. §103(a)

Claims 1, 4-7, 10-17, 35-39, 43, 44, 48 and 49 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent 5,075,226 (hereinafter "Kaneko *et al*").

Applicants respectfully disagree and traverse this rejection.

The claims as currently amended are drawn to a starter culture composition comprising a modified lactic acid bacterial cell that is harvested following treatment with a medium comprising a porphyrin compound which includes iron. Applicants respectfully submit that there is no teaching in Kaneko *et al*, nor a suggestion to modify the teachings of Kaneko *et al*, to obtain the claimed invention.

Kaneko *et al* describe the use of bacterial cultures to produce diacetyl and acetoin (See Kaneko *et al*, Col. 3-4). These bacterial cultures as described by Kaneko *et al* are used to produce diacetyl and acetoin, and there is no discussion or contemplation of the isolation or harvesting of these bacteria from the end products *following completion of the fermentation process* described in Kaneko *et al*. (See Kaneko *et al*, Examples 1-5). As a result, not all of the claim elements are taught or suggested by Kaneko *et al*, and Applicants submit that the claims as amended are not rendered obvious by Kaneko *et al*.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants

would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

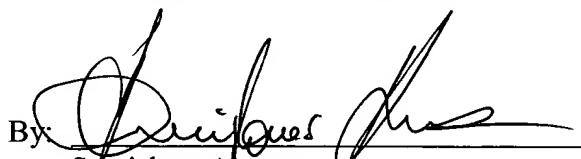
It is believed that all necessary fees are enclosed. However, if any additional fees are determined to be required, the Commissioner is hereby authorized to charge these fees to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: September 26, 2005

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Appendix

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1. Approximately; nearly: *The interview lasted about an hour.*
2. Almost: *The job is about done.*
3. To a reversed position or direction: *Turn about and walk away slowly.*
4. In no particular direction: *wandering about with no place to go.*
5. All around; on every side: *Let's look about for help.*
6. In the area or vicinity; near: *spoke to a few spectators standing about.*
7. In succession; one after another: *Turn about is fair play.*
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 - a. On the verge of; presently going to. Used with the infinitive: *The chorus is about to sing.*
 - b. Usage Problem. Used to show determination or intention in negative constructions with an infinitive: *I am not about to concede the point.*

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1. On all sides of; surrounding: *I found an English garden all about me.*
2. In the vicinity of; around: *explored the rivers and streams about the estate.*
3. Almost the same as; close to; near.

4.
 - a. In reference to; relating to; concerned with: *a book about snakes*.
 - b. In the act or process of: *While you're about it, please clean your room.*
5. In the possession or innate character of: *Keep your wits about you.*

adj.

1. Moving here and there; astir: *The patient is up and about.*
2. Being in evidence or existence: *Rumors are about concerning his resignation.*

[Middle English, from Old English *onbūtan* : *on, in*; see **on** + *būtan*, *outside*; see *ud-* in Indo-European Roots.]

Usage Note: The construction *not about to* is often used to express determination: *We are not about to negotiate with terrorists.* A majority of the Usage Panel considers this usage acceptable in speech but not in formal writing. *About* is traditionally used to refer to the relation between a narrative and its subject: *a book about Cézanne; a movie about the Boston Massacre.* This use has lately been extended to refer to the relation between various nonlinguistic entities and the things they make manifest, as in *The party was mostly about showing off their new offices* or *His designs are about the use of rough-textured materials.* This practice probably originates with the expression *That's what it's all about*, but it remains controversial. Fifty-nine percent of the Usage Panel rejected this use in the example *A designer teapot isn't about making tea; it is about letting people know that you have a hundred dollars to spend on a teapot.*

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about

In addition to the idioms beginning with **about**, also see at about; beat about the bush; bring about; cast

about; come about; do an about-face; get about; go about (one's business); how about (that); just about; knock about; lay about; man about town; nose about (around); no two ways about it; order someone about; out and about; see about; send someone about someone's business; set about; that's about the size of it; up and about; what about someone (something).

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about

adj : on the move; "up and about"; "the whole town was astir over the incident" [syn: about(p), astir(p)] adv 1: (of quantities) imprecise but fairly close to correct; "lasted approximately an hour"; "in just about a minute"; "he's about 30 years old"; "I've had about all I can stand"; "we meet about once a month"; "some forty people came"; "weighs around a hundred pounds"; "roughly \$3,000"; "holds 3 gallons, more or less"; "20 or so people were at the party" [syn: approximately, close to, just about, some, roughly, more or less, around, or so] 2: all around or on all sides; "dirty clothes lying around (or about)"; "let's look about for help"; "There were trees growing all around"; "she looked around her" [syn: around] 3: in the area or vicinity; "a few spectators standing about"; "hanging around"; "waited around for the next flight" [syn: around] 4: to or among many different places or in no particular direction; "wandering about with no place to go"; "people were rushing about"; "news gets around (or about)"; "traveled around in Asia"; "he needs advice from someone who's been around"; "she sleeps around" [syn: around] 5: in or to a reversed position or direction; "about face"; "brought the ship about"; "suddenly she turned around" [syn: around] 6: in rotation or succession; "turn about is fair play" 7: (of actions or states) slightly short of or not quite accomplished; 'near' is sometimes used informally for 'nearly' and 'most' is sometimes used informally for 'almost'; "the job is (just) about done"; "the baby was almost asleep when the alarm sounded"; "we're almost finished"; "the car all but ran her down"; "he nearly fainted"; "talked for nigh onto 2 hours"; "the recording is well-nigh perfect"; "virtually all the parties signed the contract"; "I was near exhausted by the run"; "most everyone agrees" [syn: just about, almost, most, all but, nearly, near, nigh, virtually, well-nigh]

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